B.1 510(k) Summary of Safety & Effectiveness

(as required by 21 CFR § 807.92c)

Date Prepared: April 14, 2009

JUN - 4 2009

Submitted by:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730, USA

Name, Title and Phone Number of Contact:

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Trade Name and Common Name:

Trade Name:	R2 DigitalNow™ HD (DigitalNow™ HD)
Software Version:	1.0
Common Name:	Picture Archiving and Communications System

Classification:

Regulatory Class:	II
Classification Panel:	Radiology

Image Processing System 21 CFR § 892.2050 Product Code 90-LLZ

Predicate Devices:

The predicate device for DigitalNow HD software is certain software functions contained in the following device:

K080351, Apr 22, 2008 DexTop Mammography Workstation [Dexela Limited]

Device Description:

R2 DigitalNow HD is a software application intended to process digitized screen-film mammograms.

DigitalNow HD has been designed and will be manufactured in accordance with the following standards:

• ISO 13485	Medical Devices – Quality Management Systems
• ISO 14971	Medical Devices – Application of Risk Management to Medical Devices
• ANSI/AAMI SW68:2001	Medical Device Software – Software Life Cycle Processes
• 21 CFR § 820	US Food and Drug Administration, Quality System Regulation
• N/A	General Principles of Software Validation; Final Guidance for Industry and FDA

The performance of the software is also tested in accordance with Hologic's SOPs and testing procedures to demonstrate adequate performance.

Intended Use:

R2 DigitalNow HD is a software application intended to process digitized screen-film mammograms for comparison purposes only. The software processes digitized prior film images to produce lossy-compressed DICOM images that more closely resemble digital mammography images. R2 DigitalNow HD images are intended for comparison purposes only and cannot be used for primary diagnosis.

DigitalNow HD is a software application which runs on the Hologic Cenova server (Class I exempt per 21 CFR § 892.2010 and 21 CFR § 892.2020).

Technological Characteristics:

DigitalNow HD is a software application intended to process digitized screen-film mammograms. The device does not contact the patient, nor does it control any life-sustaining devices.

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device.
Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

Conclusion:

The 510(k) Pre-Market Notification for DigitalNow HD contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.
The submission contains the results of a hazard analysis and the "Level of Concern" for potential hazards has been classified as "Moderate".

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2009

Hologic, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091368
Trade/Device Name: R2 DigitalNow™ HD (DigitalNow™ HD)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 23, 2009
Received: May 26, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

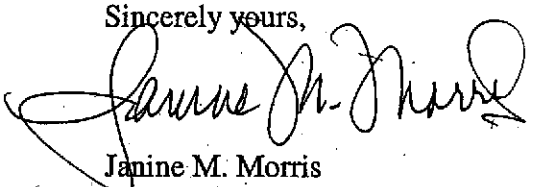
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B.2 Indication(s) for Use Statement

510(k) Number (if known): K091368

Device Name: R2 DigitalNow™ HD (DigitalNow™ HD)

Indications for Use:

R2 DigitalNow HD is a software application intended to process digitized screen-film mammograms for comparison purposes only. The software processes digitized prior film images to produce lossy-compressed DICOM images that more closely resemble digital mammography images. R2 DigitalNow HD images are intended for comparison purposes only and cannot be used for primary diagnosis.

DigitalNow HD is a software application which runs on the Hologic Cenova server (Class I exempt per 21 CFR § 892.2010 and 21 CFR § 892.2020).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091368